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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/772,607	01/30/2001	Ib Jonassen	4409-214-US	2082

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EXAMINER	
KAM, CHIH MIN	
ART UNIT	**PAPER NUMBER**
1656	

DATE MAILED: 12/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

500

Office Action Summary	Application No.	Applicant(s)	
	09/772,607	JONASSEN ET AL.	
	Examiner	Art Unit	
	Chih-Min Kam	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *48-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *48-55 and 57-59* is/are rejected.

7)☒ Claim(s) *56* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 48-59 are pending.

Applicants' response filed September 29, 2005 is acknowledged and has been fully considered. Thus, claims 48-59 are examined.

Withdrawn Claim Rejections-Obviousness Type Double Patenting

2. The previous rejection of claims 48-55 and 57-59 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of co-pending application 10/285,079 (published as 2003/0199672), is withdrawn in view of applicants' response at page 5 in the amendment filed December 15, 2004.

Maintained Claim Rejections-Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 48-55 and 57-59 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 5-7 and 15 of co-pending application 09/757,788 (published as US 2001/0012829) based on the amendment filed

September 29, 2005. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 48-55 and 57-59 in the instant application disclose a derivative of GLP-1 or an analog thereof having a lipophilic substituent which contains 8 to 40 carbon atoms, optionally has an amino group, and is attached to the C-terminal amino acid of GLP-1 or analog thereof optionally via a spacer, wherein the spacer is Lys, Glu, Asp, Glu-Lys or Asp-Lys; and the specification of the instant application discloses a pharmaceutical composition comprising the derivative of GLP-1 or an analog thereof and a carrier, which can be used for nasal administration (page 7, line 5-37). This is obvious in view of claims 1-3, 5-7 and 15 of the co-pending application which disclose a formulation suitable for pulmonary administration to a subject, said formulation comprising a GLP-1 compound having attached thereto a lipophilic substituent comprising 14-18 carbon atoms optionally via spacer, wherein the formulation upon nebulization achieves a mass medium aerodynamic diameter of less than 10 μm. Since the instant application discloses the same GLP-1 compound and liquid composition as the co-pending application, thus it would be obvious that the formulation would achieve a mass medium aerodynamic diameter of less than 10 μm upon nebulization; and since both sets of claims are directed to a derivative of GLP-1 or an analog thereof having a lipophilic substituent at C-terminus, or a formulation containing the GLP-1 derivative. Therefore, claims 48-55 and 57-59 in instant application and claims 1-3, 5-7 and 15 of the co-pending application are obvious variations of a derivative of GLP-1 or an analog thereof having a lipophilic substituent, and a formulation containing the GLP-1 derivative.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicants indicate claim 1 of copending application 09/757,788 as amended on September 29, 2005 to include the limitation "wherein said formulation upon nebulization achieves a mass medium aerodynamic diameter of less than 10 μm" of claim 17, which was not included in the rejection of obviousness-type double patenting (pages 5-6 of the response).

Applicants' response has been fully considered. However, the argument is not found persuasive because the instant application discloses the same formulation containing the same GLP-1 compound as the application 09/757,788, and the specification of the instant application also indicates the GLP-1 compound can be used for nasal administration, thus it would be obvious that the formulation would achieve a mass medium aerodynamic diameter of less than 10 μm upon nebulization. Therefore, the claims of the instant application are obvious variations over the claims of 09/757,788.

Maintained Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 48 and 49 are rejected under 35 U.S.C. 102(b) as anticipated by Habener (U.S. Patent 5,118,666, publication date: June 2, 1992).

Habener teaches a GLP-1 derivative having a formula H_2N-X-CO-R^1, where X is the peptide comprising the sequence His-Ala-Glu-Gly-Thr-Phe-Thr-Ser-Asp-Val-Ser-Ser-Tyr-Leu-Glu-Gly-Gln-Ala-Ala-Lys-Glu-Phe-Ile-Ala-Trp-Leu-Val-Lys-Arg; R^1 is OH, OM or $-NR^2R^3$;

and M is a pharmaceutically acceptable cation or a lower branched or unbranched alkyl group; R^2 and R^3 are hydrogen or a lower branched or unbranched alkyl group (column 3, lines 6-46). Since the art recognizes the lower alkyl group can be C_{1-8} or C_{1-12} (see the reference in the Art of Record), and the lower alkyl group is attached to the C-terminus amino acid without a spacer, thus the GLP-1 derivative taught by Habener *et al.* meets the criteria of claims 48 and 49.

Response to Arguments

Applicants indicate the cited Habener '666 patent states that "alkyl can be C_1-C_{12}" (col. 6, lines 25-26), it must logically follow that the use of "lower alkyl in the '666 patent must mean something less than 12 carbons. The '458 patent cited by the Examiner is not relevant to what one skilled in the art in the field of GLP-1 peptide. Regarding the phrase "lower alkyl" in the '666 patent, one skilled in the art would look to patents in the field of GLP-1 peptides, e.g., US patent 5,120,712 ('712 patent, filed 6/1/90), states that "lower alkyl" is C_1-C_6 (see col. 4, lines 21-25 of the '712 patent). Further evidence that the "lower alkyl" in the Habner '666 patent means C_1-C_6 alkyl to one skilled in the art in the field of GLP-I peptides is provided by US patent 6,828,303 which describes the "lower alkyl" as being C_1-C_6 alkyls (see col. 1, lines 55-67 of USP 6,828,303). Since "lower alkyl" in the Habener '666 patent means C_1-C_6 alkyl, Habener cannot be held to anticipate claims 48-49 of the present application (pages 4-5 of the response).

Applicants' response has been fully considered. However, the argument is not found persuasive because of the following reasons: First, "alkyl can be C_1-C_{12}" (col. 6, lines 25-26) cited in the Habener '666 patent merely identifies the alkyl group being C_1-C_{12} in the compounds of tetraalkylammonium and trialkylammonium, the term is not relevant to whether the C_1-C_{12} is lower alkyl group or not. Secondly, the term "lower alkyl" is generally used to identify a

substituent in various types of compounds including GLP-1, unless the term is specifically defined in the compound, the term can mean C_1-C_6 (e.g., in USPN 5,120,712), C_1-C_8 or C_1-C_{12} (e.g., in USPN 5,118,666; 3,567,450, col. 3, lines 26-28). Regarding the patent 6,828,303, it is a post filing reference and is not considered. Since Habener '666 patent does not specifically define the term as C_1-C_6, it can be read as C_1-C_8 or C_1-C_{12}. Therefore, the claimed GLP-1 compounds are anticipated by the Habener '666 patent

Claim Objection

5. Claim 56 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusions

6. Claims 48-55 and 57-59 are rejected, and claim 56 is objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Patent Examiner

CHIH-MIN KAM
PATENT EXAMINER

CMK
November 19, 2005